PATENT
Attorney Docket No. 401371/NIH
DHHS Reference: E-105-99/0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BURKE, Jr., et al.

Group Art Unit: 1653

Application No. 09/937,150

Examiner: David Lukton

Filed: September 21, 2001

For: PHENYLALANINE DERIVATIVES

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☐ the fee of $180 set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of $180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of $180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith.

☐ A copy of the foreign search report is enclosed herewith.

☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status *(check one)*		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

☒ **No fee** is owed by the applicant(s).
☐ The **IDS Fee of $180** under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

☐ Attached is a check in the amount of $.
☐ Charge Deposit Account No. 12-1216 in the amount of $. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of BURKE, Jr., et al.
Application No. 09/937,150

Instructions as to Overpayment

☒ Credit Account No. 12-1216.
☐ Refund

Respectfully submitted,

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IDS (Rev. 2/1/2001)

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 10

Complete if Known	
Application Number	09/937,150
Filing Date	September 21, 2001
First Named Inventor	Terrence R. Burke, Jr.
Group Art Unit	1653
Examiner Name	David Lukton
Attorney Docket Number	401371/NIH

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document: Application or Patent Number	U.S. Patent Document: Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
	A1	3,906,031		Carpino et al.		
	A2	4,394,519		Carpino et al.		
	A3	4,879,398		Getman et al.		
	A4	5,182,263		Danho et al.		
	A5	5,200,546		Burke, Jr. et al.		
	A6	5,272,268		Toyoda et al.		
	A7	5,296,608		Danho et al.		
	A8	5,369,110		Schmidlin et al.		
	A9	5,457,114		Stüber et al.		
	A10	5,463,062		Hemmerle et al.		
	A11	5,491,253		Stuk et al.		
	A12	5,508,437		Danho et al.		
	A13	5,525,733		Novack et al.		
	A14	5,612,370		Atwal		
	A15	5,580,979		Bachovchin		
	A16	5,587,372		Aszodi et al.		
	A17	5,616,776		Stuk et al.		
	A18	5,627,283		Stüber et al.		
	A19	5,646,036		Schwall et al.		
	A20	5,679,842		Kleiner		
	A21	5,686,292		Schwall et al.		
	A22	5,688,992		Burke, Jr. et al.		
	A23	5,698,731		Bosetti et al.		
	A24	5,707,624		Nickoloff et al.		
	A25	5,710,129		Lynch et al.		
	A26	5,710,173		Tang et al.		
	A27	5,712,395		App et al.		
	A28	5,753,687		Mjalli et al		
	A29	5,756,817		Choi et al.		
	A30	5,773,411		Wells et al		
	A31	5,780,496		Tang et al.		
	A32	5,786,454		Waksman et al.		
	A33	5,789,427		Chen et al.		
	A34	5,792,771		App et al.		
	A35	5,792,783		Tang et al.		
	A36	5,834,504		Tang et al.		
	A37	5,843,997		Heinz et al.		
	A38	5,849,693		Wells et al.		
	A39	5,849,742		App et al.		
	A40	5,880,141		Tang et al.		

Examiner Signature		Date Considered	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

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	A41	5,883,110		Tang et al.		
	A42	5,883,113		Tang et al.		
	A43	5,883,116		Tang et al.		
	A44	5,886,020		Tang et al.		
	A45	5,886,195		Tang et al.		
	A46	5,891,917		Tang et al.		
	A47	5,912,183		Comoglio et al.		
	A48	5,935,993		Tang et al.		
	A49	5,958,957		Andersen et al.		
	A50	5,965,558		Mjalli et al.		
	A51	5,972,978		Andersen et al.		
	A52	5,981,569		App et al.		
	A53	6,037,134		Margolis		
	A54	6,228,986		Lanter et al.		
	A55	6,307,090		Burke et al.		

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document: Office	Foreign Patent Document: Application or Patent Number	Foreign Patent Document: Kind Code	Name of Patentee or Applicant	Date of Publication	Translation: Yes	Translation: No*+
	A56	PCT	WO 94/07913		Dobrusin et al.	04/14/94		
	A57	PCT	WO 95/11917		Bolton et al.	05/04/95		
	A58	PCT	WO 96/23813		Patel et al.	08/08/96		
	A59	PCT	WO 97/08193		Garcia-Echeverria et al.	03/06/97		
	A60	PCT	WO 00/73326		Roller et al.	12/07/00		

OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation: Yes	Translation: No*+
	A61	Ye et al., "L-*O*-(2-Malonyl)tyrosine" A New Phosphotyrosyl Mimetic for the Preparation of Src Homology 2 Domain Inhibitory Peptides", J. Med. Chem. Vol. 38, pp. 4270-4275, 1995		
	A62	Burke, Jr., et al., "4'-*O*-[2-(2-Fluoromalonyl)]-L-tyrosine: A Phosphotyrosyl Mimic for the Preparation of Signal Transduction Inhibitory Peptides", J. Med. Chem., Vol. 39, pp 1021-1027, March 1, 1996		
	A63	Schoepfer et al., "Structure-based Design of Peptidomimetic Ligands of Grb2-SH2 Domain", Bioorganic & Medicinal Chemistry Letters 8, pp. 2865-2870, 1998		
	A64	Yao et al., "Potent Inhibition of Grb2 SH2 Domain Binding by Non-Phosphate-Containing Ligands", J. Med. Chem., Vol. 42, pp. 25-35, 1999		
	A65	Gay et al., "Effect of Potent and Selective Inhibitors of the Grb2 SH2 Domain on Cell Motility", The Journal of Biological Chemistry, Vol. 274, pp. 23311-23315, August 13, 1999		
	A66	Schoepfer et al., "Highly Potent Inhibitors of the Grb2-SH2 Domain", Bioorganic & Medicinal Chemistry Letters 9, pp. 221-226, 1999		
	A67	Burke, Jr., et al., Monocarboxylic-Based Phosphotyrosyl Mimetics in the Design of Grb2 SH2 Domain Inhibitors", Bioorganic & Medicinal Chemistry Letters 9, pp. 347-352, 1999		
	A68	Gilmer et al., " Peptide Inhibitors of src SH3-SH2-Phosphorprotein Interactions", The Journal of Biological Chemistry, Vol. 269, pp. 31711-31719, December 16, 1994		
	A69	Charifson et al., "Peptide Ligands of pp60$^{c\text{-}src}$ SH2 Domains: A Thermodynamic and Structural Study", Biochemistry, Vol. 36, pp. 6283-6293, 1997		
	A70	Liu et al., "Synthesis of L-2,3,5,6-Tetrafluoro-4-(Phosphonomethyl) Phenylalanine, a Novel Non-Hydrolyzable Phosphotyrosine Mimetic and L-4-(Phosphonodifluoromethyl)Phenylalanine", Tetrahedron Letters, Vol. 38, pp. 1389-1392, 1997		

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Sheet 4 of 10

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	A71	Cleland, "The Meerwein Reaction in Amino Acid Synthesis. II. An Investigation of Twenty-one Substituted Anilines", The Journal of Organic Chemistry", Vo., 34, pp. 744-747, March 1969		
	A72	Gao et al., "Inhibition of Grb2 SH2 Domain Binding by Non-Phosphate-Containing Ligands. 2. 4-(2-Malonyl)phenylalanine as a Potent Phosphotyrosyl Mimetic, J. Med. Chem., Vol. 43, pp. 911-920, 2000		
	A73	Furet et al., "Structure-Based Design and Synthesis of High Affinity Tripeptide Ligands of the Grb2-SH2 Domain, J. Med. Chem., Vol. 41, pp. 3442-3449, 1998		
	A74	Tong et al., "Carboxymethyl-phenylalanine as a Replacement for Phosphotyrosine in SH2 Domain Binding", The Journal of Biological Chemistry, Vol. 273, pp. 20238-20242 August 7, 1998		
	A75	Tulasne et al., "The Multisubstrate Docketing Site of the MET Receptor is Dispensable for MET-mediated RAS Signaling and Cell Scattering", Molecular Biology of the Cell, Vol. 10, pp.551-565, March 1999		
	A76	Kim et al., "Dual Signaling Role of the Protein Tyrosine Phosphotase SHP-2 in Regulating Expression of Acute-Phase Plasma Proteins by Interleukin-6 Cytokine Receptors in Hepatic Cells", Molecular and Cellular Biology, Vol. 19, pp. 5326-5338, Aug. 1999		
	A77	Nguyen et al., "Association of the Multisubstrate Docking Protein Gab1 with the Hepatocyte Growth Factor Receptor Requires a Functional Grb2 Binding Site Involving Tyrosine 1356", The Journal of Biological Chemistry, Vol. 272, pp. 20811-20819, August 15, 1997		
	A78	Maina et al., "Uncoupling of Grb2 from the Met Receptor in Vivo Reveals Complex roles in Muscle Development", Cell, Vol. 87, pp. 531-542, Nov. 1, 1996		
	A79	Ponzetto et al., "Specific Uncoupling of GRB2 from the Met Receptor", The Journal of Biological Chemistry, Vol. 271, pp. 14119-14123, June 14, 1996		
	A80	Ettmayer et al., "Structural and Conformational Requirements for High-Affinity Binding to the SH2 Domain of Grb2", J. Med. Chem., Vol. 42, pp. 971-980, 1999		
	A81	Royal et al., "Differential Requirement of Grb2 and P13-Kinase in HGF/SF-Induced Cell Motility and Tubulogenesis", Journal of Cellular Physiology, Vol. 173, pp. 196-201, 1997		
	A82	Gao et al., Biorg and Med Chem Lett. 10, 923-927 (2000)		
	A83	Burke, Jr., et al., "Preparation of...Peptide Synthesis", J. of Synthetic Organic Chem., No. 11, p. 1019, Nov. 11, 1991.		

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Sheet 5 of 10

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Application Number	09/937,150
Filing Date	September 21, 2001
First Named Inventor	Terrence R. Burke, Jr.
Group Art Unit	1653
Examiner Name	David Lukton
Attorney Docket Number	401371/NIH

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes	Translation No*+
	A84	Burke, Jr., et al., "Potent Inhibition of Grb2 SH2 domain Binding by Non-Phosphate containing Ligands", First Annual Meeting on the Experimental Therapeutics of Human Cancer, June 11-13, 1998, Hood College, Frederick Maryland (Summary)		
	A85	Katunuma et al., "Use of new synthetic substrates for assays of cathepsin L and cathepsin B", J. Biochem. (Tokyo), Vol. 93, pp. 1129-35, 1983 (Abstract only)		
	A86	Burke, Jr., et al., "Enantioselective Synthesis...Inhibitory Peptides", Tetrahedron, Vol. 54, pp. 9981-9994, 1998		
	A87	Burke, Jr., et al., "Phosphotyrosyl-Based Motifs in the Structure-Based Design of Protein-Tyrosine Kinase-Dependent Signal Transduction Inhibitors", Current Pharmaceutical Design, Vol. 3, pp. 291-304, 1997		
	A88	Burke, Jr., et al., "Nonhydrolyzable Phosphotyrosyl Mimetics for the Preparation of Phosphatase-Resistant SH2 Domain Inhibitors", Biochemistry, Vol. 33, pp. 6490-6494, 1994		
	A89	Ye et al., "L-O-(2-Malonyl)tyrosine (L-OMT) a New Phosphotyrosyl Mimic Suitably Protected for Solid-Phase Synthesis of Signal Transduction Inhibitory Peptides", Tetrahedron Letters, Vol. 36, pp. 4733-4736, 1995		
	A90	Kuriyan, "Modular Peptide recognition Domains in Eukaryotic Signaling", Annu. Rev. Biophys. Biomol. Struct., Vol. 26, pp. 259-88, 1997		
	A91	Mayer et al., "Functions of SH2 AND SH3 Domains", Protein modules in signal transduction, edited by A. J. Pawson, Berlin, New York, Springer, c1998, pp. 1-22		
	A92	Fry et al., "New insights into protein-tyrosine kinase receptor signaling complexes", Protein Science, Vol. 2, pp. 1785-1797, 1993		
	A93	Levitzki, "Targeting signal transduction for disease therapy", Current Opinion in Cell Biology, Vol. 8, pp. 239-244, 1996		
	A94	Boutin, "Tyrosine Protein Kinase Inhibition and Cancer", Int. J. Biochem., Vol. 26, pp. 1203-1226, 1994		
	A95	Levizski et al., "Tyrosine Kinase Inhibition: An Approach to Drug Development", Science, Vol. 267, pp. 1782-1788, March 24, 1995		
	A96	Lawrence et al., "Protein Kinase Inhibitors: The Tyrosine-specific Protein Kinases", Pharmacol. Ther., Vol. 77, pp. 81-114, 1998		
	A97	Burke, Jr., et al., "Protein-Tyrosine Phosphatases: Structure, Mechanism, and Inhibitor Discovery", Biopolymers (Peptide Science), Vol., 47, pp. 225-241 (1998)		
	A98	Schoelson, "SH2 and PTB domain interactions in tyrosine kinase signal transduction", Current Opinion in Chemical Biology, Vol. 1, pp. 227-234, 1997		

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Sheet	6	of	10	Attorney Docket Number	401371/NIH

OTHER - NON PATENT LITERATURE DOCUMENTS				
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	A99	Waksman et al., "Crystal structure of the phosphotyrosine recognition domain Sh2 of v-src complexed with tyrosine-phosphorylated peptides", Nature, Vol. 358, pp. 646-653, Aug. 20, 1992		
	A100	Waksman et al., "Binding of High Affinity Phosphotyrosyl Peptide to the Src SH2 Domain: Crystal Structures of the Complexed and Peptide-free Forms", Cell, Vol. 72, pp. 779-790, March 12, 1993		
	A101	Mikol et al., "The Crystal Structures of the SH2 Domain of $p56^{ick}$ Complexed with Two Phosphonopeptides Suggest a Gated Peptide Binding Site", J. Mol. Biol. Vol. 246, pp. 344-355, 1995		
	A102	Hatada et al., "Molecular basis for interaction of the protein tyrosine kinase ZAP-70 with the T-cell receptor", Nature, Vol. 377, pp. 32-38, Sept. 7, 1995		
	A103	Zhou et al., "Solution structure of the Shc SH2 domain complexed with a tyrosine-phosphorylated peptide from the T-cell receptor", Proc. Natl. Acad. Sci., Vol. 92, pp. 7784-7788, August 1995		
	A104	Narula et al., "Solution structure of the C-terminal SH2 domain of the human tyrosine kinase Syk complexed with a phosphotyrosine pentapeptide", Structure, Vol. 3, 1061-1073, Oct. 15, 1995		
	A105	Xu et al., "Solution Structure of the Human $pp60^{c\text{-}src}$ SH2 Domain Complexed with a Phosphorylated Tyrosine Pentapeptide", Biochemistry, Vol. 34, pp. 2107-2121, 1995		
	A106	Tong et al., "Crystal Structures of the Human $p56^{lck}$ SH2 Domain in Complex with Two Short Phosphotyrosyl Peptides at 1.0 Å and 1.8 Å Resolution", Academic Press Limited, 10 pages, 1996.		
	A107	Sicheri et al., "Crystal structure of the Src family tyrosine kinase Hck", Nature, Vol. 385, pp. 602-609, Feb. 13, 1997		
	A108	Chen et al., "Crystal Structure of a Tyrosine Phosphorylated STAT-1 Dimer Bound to DNA", Cell, Vol. 93, pp. 827-839, May 29, 1998		
	A109	Songyang et al., "Recognition and specificity in protein tyrosine kinase-medicated signalling", Elsevier Science Ltd., pp. 470-475, 1995		
	A110	Lunney et al., "Structure-Based Design of a Novel Series of Nonpeptide Ligands That Bind to the $pp60^{src}$ SH2 Domain", J. Am. Chem. Soc., Vol. 119, pp. 12471-12476, 1997		
	A111	Pacofsky et al., "Potent Dipeptide Inhibitors of the $pp60^{c\text{-}src}$ SH2 Domain", J. Med. Chem., Vol. 41, pp. 1894-1908, 1998		
	A112	Marseigne et al., "Synthesis of New Amino Acids Mimicking Sulfated and Phosphorylated Tyrosine Residues", J. Org. Chem., Vol. 53, pp. 3621-3624, 1988		
	A113	Domchek et al., "Inhibition of SH2 Domain/Phosphoprotein Association by a Nonhydrolyzable Phosphonopeptide", Biochemistry, Vol. 31, pp. 9865-9870, 1992		

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				Filing Date	September 21, 2001
				First Named Inventor	Terrence R. Burke, Jr.
				Group Art Unit	1653
(Use as many sheets as necessary)				Examiner Name	David Lukton
Sheet	7	of	10	Attorney Docket Number	401371/NIH

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes	Translation No*+
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U.S. PATENT DOCUMENTS

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